

These comments add to those provided by Rick Solana in his e-mail to Brendan McCormick on November 27, 2002.

On the 1st VCU article mentioned by the VCU press release dated Nov. 22, 2002:

- At this time only 1 (Breland et al., *Tobacco Control* 2002, 11:376-378) of the 2 new publications referenced in the press is actually published.
- The article published in the December issue of *Tobacco Control* reports data only on *Advance*.
- The researchers have basically used the same set of investigations (heart rate measurements, biomarker measurements and questionnaires for 'cigarette cravings and withdrawal' for the new study on *Advance* they used in earlier studies on *Accord* that were published in 2001.
- The *Advance* study is one of several investigations (here on 'acute effects') of these new products; its data and interpretation is obviously limited to its specific design. For a few study design parameters we might take approaches different from the researchers (e.g., the occlusion of filter vent holes).
- We agree with the statements at the end of the discussion that 'Understanding the risks associated with widespread PREP use requires careful, objective evaluation.' and '... might involve acute and longer term studies of PREPs that are carried out before the products are marketed, under strict regulatory oversight, and with clear assessment methods'. This reflects our own approach, current practice, and support for meaningful Federal regulation.
- In accordance with the recommendations by the IOM in its report *Clearing the Smoke, 2001*, we see the evaluation of PREPS before they are marketed with any claims as a responsibility of the manufacturers. Post-market surveillance of the use and of the smoking behavior as they relate to the claimed reduced exposure or risk reduction should also be undertaken by the manufacturer. The results of such studies should be published in peer-reviewed scientific journals.

On the unpublished 2nd article mentioned in the press release dated November 22, 2002 ¹:

¹ 'Pre-print' without figures provided to us by the source quoted in the press release.